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APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. **FILING DATE** 10/025,333 Mahendra S. Rao UT-0037 4765 12/19/2001 7590 **EXAMINER** 01/05/2005 Licata & Tyrrell P.C. HAYES, ROBERT CLINTON 66 E. Main Street Marlton, NJ 08053 **ART UNIT PAPER NUMBER** 1647 DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Application No. Applicant(s)	
Office Action Summary	10/025,333	RAO ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	
The MAILING DATE of this communication Period for Reply	n appears on the cover sheet wit	the correspondence address	
A SHORTENED STATUTORY PERIOD FOR RETHE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CF after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days,  - If NO period for reply is specified above, the maximum statutory period for reply within the set or extended period for reply will, by so any reply received by the Office later than three months after the rearned patent term adjustment. See 37 CFR 1.704(b).	ON. FR 1.136(a). In no event, however, may a rent in. In a reply within the statutory minimum of thirty eriod will apply and will expire SIX (6) MONT statute, cause the application to become ABA	oly be timely filed  (30) days will be considered timely.  HS from the mailing date of this communic  NDONED (35 U.S.C. § 133).	cation.
Status			
1) Responsive to communication(s) filed on (	<u>04 November 2004</u> .		
2a) ☐ This action is <b>FINAL</b> . 2b) ☒	This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
<ul> <li>4)  Claim(s) 21-34 is/are pending in the application 4a) Of the above claim(s) 21-32 is/are with 5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 33 and 34 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) 21-34 are subject to restriction are</li> </ul>	drawn from consideration.		
Application Papers	•		
9) The specification is objected to by the Exar	miner.		
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the co		•	` '
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for form  a) All b) Some * c) None of:  1. Certified copies of the priority docum  2. Certified copies of the priority docum  3. Copies of the certified copies of the application from the International But  * See the attached detailed Office action for a	nents have been received. nents have been received in Appriority documents have been received in Appriority documents have been received.	plication No eceived in this National Stage	•
Attachment(s)			•
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> </ol>	•	mmary (PTO-413) Mail Date	
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SE Paper No(s)/Mail Date <u>2/21/02</u> .	<i>'</i>	ormal Patent Application (PTO-152)	

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## **DETAILED ACTION**

### Election/Restriction

Applicant's election with traverse of Group II (claim 34) in Paper No: 11/04/04 is 1. acknowledged. The traversal is on the ground(s) that "[s]earching for art relating to the cells of Groups I or II will clearly reveal any art relating to methods for isolation thereof as set forth in Groups III and IV, respectively or cells derived therefrom as set forth in Group V", and that "the application is a continuation application of U.S. Patent Application Serial No. 08/852,744 and a search by the Examiner of the instant application of prior art relating to mammalian CNS neuroepithelial stem cells and mammalian CNS glial-restricted precursor cells was already performed. Thus, no serious burden is placed upon the Examiner by including all Groups, or at least Groups I and II, in the prosecution of this case. This is not found persuasive because the methods of Groups III, IV & V require different starting materials, etc. (e.g., co-cultures, antibodies, or motoneurons, protocols, etc.) not required in Group II. A serious burden further exists because of the different goals and method steps required for the claims of Groups III, IV & V, which are not required for examination of the products of Group II, and for the reasons previously made of record in Paper No: 20040930. In contrast, Applicants' arguments are persuasive for re-joining Groups I (claim 34) and II (claim 33). However, the remaining restriction requirement is still deemed proper and is therefore made FINAL.

Claims 21-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No: 10/04/04.

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## **Double Patenting**

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33 & 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 & 15, respectively, of U.S. Patent No. 6,361,996 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sole difference between the instant claims and that claimed in '996 is the broadening of that claimed to the generic recitation of "mammalian... cells", versus "rat... cells" as patented in '996.

It is also suggested that line 2 of claim 34 be amended to "derived from [a] the neural tube...", in order to be more grammatically consistent with claim 33.

#### Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Johe et al. U.S. Patent 5,753,506.

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-although Johe et al describe a "homogeneous population of rapidly dividing cells expressing nestin...characteristic for CNS precursor cells. Less than 1% of the cells [alternatively] expressed the astroglial marker GFAP or the oligodendroglial markers, O4 and GalC." (col. 13, lines 34-39). Therefore, Johe's "homogeneous population of... CNS stem cells that can be differentiated into neurons, oligodendrocytes, and astrocytes..." (col. 12, lines 29-34) are not a "pure, homogeneous population of mammalian neuroepithelial stem cells...", as currently claimed, due to the presence of other differentiated cell types in Johe's otherwise homogeneous population of precursor cells. Additionally, Johe disclose that "[n]o simple antigenic marker is available which uniquely identifies multipotential stem cells from other precursors in vitro..." (col. 13, lines 59-62). Accordingly, Johe's homogeneous population of cells contain other "undifferentiated" precursor cells (e.g., col. 20, lines 40-42), such as the glial-restricted precursor cells of claim 34; thereby, distinguishing the instant inventions from that taught by Johe et al.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D. December 28, 2004

ROBERT C. HAYES, PH.D. PATENT EXAMINER